**UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)**

TRIANTAFYLLOS TAFAS, **Plaintiff,** **v.** **JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,** **Defendants.**	**CIVIL ACTION: 1:07cv846 (JCC/TRJ) and Consolidated Case (below)**
SMITHKLINE BEECHAM CORPORATION, **Plaintiff,** **v.** **JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,** **Defendants.**	

**PLAINTIFF TRIANTAYLLOS TAFAS' REPLY TO DEFENDANTS' MEMORANDA
IN OPPOSITION TO PLAINTIFFS' SUMMARY JUDGMENT MOTIONS**

Steven Moore, Esq. (*Pro Hac Vice*) James E. Nealon, Esq. (*Pro Hac Vice*) William R. Golden Jr., Esq. (Of Counsel) KELLEY DRYE & WARREN LLP 101 Park Avenue New York, New York 10178-0002 Telephone: (212) 808-7992 Facsimile: (212) 808-7897 E-mail: smoore@kelleydrye.com jnealon@kelleydrye.com wgolden@kelleydrye.com	Joseph Dale Wilson, III, Esq. (VSB#43973) KELLEY DRYE & WARREN LLP Washington Harbor, Suite 400 3050 K Street, NW Washington, DC 20007 Telephone: (202) 342-8400 Facsimile: (202) 342-8451 E-mail: jwilson@kelleydrye.com

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PRELIMINARY STATEMENT

The Plaintiff, Dr. Trianatfyllos Tafas ("Dr. Tafas") submits this reply to Defendants' Memoranda in Opposition to Tafas' and GSK's Motions for Summary Judgment dated January 22, 2008 (Docket Nos. 247 and 246, respectively).[1]

As stated so eloquently by *amicus* Elan Pharmaceutical during the hearing that preceded the Court preliminarily enjoining the USPTO's new rules in Tafas v. Dudas, 511 F. Supp.2d 652 (E.D.V.A. 2007)("Tafas I"), the development and future availability of cutting edge, desperately needed life-saving medical advances may well turn on whether the USPTO succeeds in upholding its new rules, which are designed to serve the USPTO's own administrative convenience at the expense of innovation:

> [I]f these rules go into effect tomorrow…there will be much less incentive for pharmaceutical companies, biotech companies, and all innovators to develop new drugs. Because if there is not going to be robust patent protection -- these companies spend millions, billions of dollars on research and development each year. Without patent protection to protect that investment, there will be less incentive to do that. That means there will be less drugs to help -- lifesaving drugs to help the public in the future…

October 31, 2007 Preliminary Injunction Hearing Tr. at pp. 37-38.

As part of a cynical misdirection play, the USPTO and its small group of *amici* have jumped on the "research for nothing" bandwagon and disingenuously sought to mischaracterize this case as one involving "special interests" (e.g., the pharmaceutical companies) seeking to block the USPTO's rules solely to perpetuate their own selfish interests to

[1] Rather than file a single brief, the USPTO filed separate memoranda in opposition to Tafas' and GSK's motions for summary judgment. The USPTO addressed all arguments raised by both Tafas and GSK in its Memorandum In Opposition to GSK's Motion for Summary Judgment (No. 246)("USPTO Opp. Mem. I") and addressed only the additional arguments raised exclusively by Tafas in the USPTO's Memorandum in Opposition to Tafas' Motion for Summary Judgment (No. 247)("USPTO Opp. Mem. II").

the detriment of the public. Nothing could be further from the truth. These new rules will have a draconian adverse effect on businesses and inventors of all stripes -- large and small.

Defendants castigate GSK suggesting that arguments made by such "industry giants" should be taken with a "grain of salt" because they are not congruous with the views of "entrepreneurs who are considering starting and expanding businesses." [2] The disingenuous nature of the USPTO's purported concern for individual inventors and small businesses is amply demonstrated by the fact that Defendants have condescendingly sought to ignore Dr. Tafas throughout these proceedings notwithstanding that he is the very type of small entrepreneur the USPTO contends somehow benefit from the new rules.

It was Dr. Tafas -- an entrepreneur, an immigrant, a former professor of the University of Athens -- who could not take solace in his name being hidden behind the facade of a multi-billion dollar company being the named plaintiff, who was the first to challenge the USPTO's new rules. Tafas filed this action because of his heart felt belief that the U.S. patent system, and the protections and benefits it affords small companies and independent inventors, was essentially being radically dismantled by the USPTO in a misguided and misdirected effort to rid itself of a self-induced backlog of unexamined patent applications. Dr. Tafas challenged the Final Rules in part to thank his new country (the U.S.) for affording him the opportunity to pursue a dream effectively denied to him under the far more restrictive, big business oriented patent systems of Europe, and his native country, Greece, that is, of obtaining the capital and support necessary for the development of a radical invention -- a robotic microscope capable of automatically reading and analyzing tissues on microscope slides.

[2] Def's Opp. Mem. to Plaintiff's Motion for TRO and Preliminary Injunction at 38.

Dr. Tafas' present research relates to the use of his robotic microscope, along with proprietary cell labels to detect cancer in a very early stage by monitoring blood samples that could be taken and analyzed in the future as part of routine medical visits. His system holds out the promise of a cost effective technique that could be applied on a mass scale to detect early stage cancers before they metastasize and become effectively untreatable. Dr. Tafas knows that he was able to obtain the capital he needed to start and grow his company (Ikonysis, Inc.) because of a patent system that equally balanced the rights of large and small companies and provided the protections necessary so that investors were willing to make an informed gamble on the dreams of one wide-eyed scientist, and a relatively few patent applications.

Dr. Tafas filed this case one (1) day after the Final Rules were published and is the original architect of the primary legal arguments now being made by himself and GSK in opposition to the new rules. Tafas continued alone in this case for nearly two months after the filing of his initial complaint and preliminary injunction motion regardless of some naysayers, who while fully supporting his main arguments, openly questioned whether a "small inventor" could possibly prevail in a challenge against the USPTO's unlimited resources and might. And although nearly everyone supported him, no one, not a single entity or party, proffered Dr. Tafas any monetary aid in his endeavor. Nevertheless, Dr. Tafas trudged on alone until GSK entered the fray in mid-October 2007.

In sum, Dr. Tafas is inconvenient for the USPTO because he cannot fairly be characterized as a huge multi-national corporation, a "patent troll," or a "crack-pot inventor." Dr. Tafas is simply the epitome of the American Dream and one of an increasingly rare breed of individuals prepared to stand for their principles, and do what they believe is right, regardless of the risk and costs to themselves, even with a recognition that in our society often only the large and powerful are ever applauded as "heroes."

ARGUMENT

A. The USPTO's Exercise Of Rulemaking Authority Is Substantive And Does Not Qualify For *Chevron* Deference

In its Notice of Rulemaking and throughout this case, the USPTO has repeatedly taken the position that its new rules are "procedural" or "interpretive" in nature[3] and, therefore, are exempt from notice and comment rulemaking under 5 U.S.C. § 553(b):

> [T]he changes being adopted in this notice do not change the substantive criteria of patent eligibility and do not effectively foreclose the applicant's opportunity to make a case on the merits (i.e., the changes in the final rules continue to provide patent applicants with numerous opportunities). Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure…Accordingly, prior notice and an opportunity for public comment were not required….

72 Fed. Reg. 161, 46830 (A.09505)(citations omitted)(emphasis added).

> These rules are procedural … they're specifically enacted pursuant to the rulemaking authority that Congress has given the PTO expressly in Section 2(b)(2) of the Patent Act … These are procedural rules in the sense they are promulgated pursuant to express authority.
>
> * * * *
>
> [T]he PTO has acted at the zenith of its authority in promulgating these rules. They are promulgated under Section 2 … the bottom line is that these are procedural rules that are exactly about governing the conduct of the proceedings of the office.

October 31, 2007 Hearing Tr. at pp. 42 and 49, respectively) (emphasis added).

Aware that it has no substantive rule making authority and obviously seeking to distance itself from its above referenced earlier admissions, the USPTO attempts to obfuscate the fact that its Final Rules are substantive (and thus not entitled to any Chevron deference) by now belatedly suggesting that the labeling of Final Rules is simply a matter of semantics. The USPTO contends that the Court need only determine whether "[C]ongress delegated rulemaking authority to the USPTO to promulgate the Final Rules" and that the procedural or substantive nature of the rules is of no moment. As discussed below, the USPTO either entirely misses the point or is once again throwing the Court a "curve ball."

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[3] Likewise, the law professor *amici* who support the USPTO concede that the only rulemaking power given to the USPTO by Congress is to "make regulations governing its internal proceedings." (Law Professor Mem. at 4)(No. 232).

The U.S. Supreme Court has made it eminently clear that a precondition for Chevron deference "is a congressional delegation of administrative authority." Adams Fruit Co. v. Barrett, 494 U.S. 638, 640 (1990). 35 U.S.C. § 2(b)(2) limits the USPTO's rule making powers to procedural matters only and does not grant the USPTO substantive or interpretative rule making powers. (See Tafas Mem. in Support of Summary Judgment dated December 20, 2007 at pp. 8-10 and Tafas Mem. in Opp. To Def. Summary Judgment Motion dated January 22, 2007 at pp. 11-18). The USPTO is not entitled to any Chevron deference where, as here, it purports to engage in substantive rule making. See Pesquera Mares Australes Ltda. v. United States, 266 F.3d 1372, 1381 n.6 (Fed. Cir. 2001) (citing Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996) for the proposition that the USPTO lacks substantive rulemaking authority, and, as such, may not claim Chevron deference for a substantive rule).

Thus, the fact that the Final Rules are substantive is a critical issue, irrespective of the USPTO's conclusory pronouncements otherwise. The Final Rules are clearly substantive, inter alia, in that they retroactively apply to pending applications (destroying the *quid pro quo* bargain for disclosing a trade secret, that is, the opportunity of future patent rights) and because they limit continuing applications, RCEs and the number of claims.[4] The Final Rules provide only illusory outlets to overcome such limitations, as amply demonstrated, inter alia, by the USPTOs own public statements to the Office of Management and Budget ("OMB") discussed infra.

[4] See A00432 (Exh. 1) – "Why Limit Continuations?" and A00434 (Exh. 1) – "Why Limit Claims?"

The Final Rules are also substantive because they inherently affect the rights and obligations of applicants and impose new conditions and burdens on the exercise of statutorily granted patent rights and benefits. See Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979) (stating that substantive rules are those that "affect [] individual rights and obligations").

Aware of the weakness of its claim of Chevron deference in procedural rulemaking, the USPTO now asserts that it actually has substantive rulemaking authority. (USPTO Opp. Mem. I at 49 n. 30). The fatal flaw with the USPTO's attempted Houdini act is that it runs smack into Federal Circuit precedent that indicates that the USPTO has no substantive rulemaking authority. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) ("the broadest of the PTO's rulemaking powers … authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [PTO]'; it does not grant the Commissioner the authority to issue substantive rules."); see also, Eli Lilly & Co. v. Bd. of Regents of the University of Washington, 334 F.3d 1264, 1269 n. 1 (Fed. Cir. 2003).

As a hedge, the USPTO argues in the alternative that Skidmore deference (as set forth in Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("Skidmore")) applies because its Final Rules are merely "interpretative." As explained in the *amicus* brief of the William Mitchell College of Law, however, Skidmore deference is only given to agency interpretations to the extent they have the "power to persuade." Christensen v. Harris Cty., 529 U.S. 576, 587 (2000). Further, as Congress has not delegated interpretative authority to the USPTO, but rather to the judiciary, Skidmore deference is simply irrelevant. See e.g., Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 161–62 (4th Cir. 1998); Sac & Fox Nation of Mo. v. Norton, 240 F.3d 1250, 1265–66 (10th Cir 2001) ("Because the Secretary lacked authority to interpret the term … we owe no deference to his interpretation").

There is no merit to the USPTO's bald contention that its Final Rules are merely "interpretative" of 35 U.S.C. §120 and other applicable Patent Act provisions. First, the Courts have already interpreted Section 120 as providing for unlimited continuations. In re Henriksen, 399 F.2d 253, 254 (C.C.P.A. 1968)[5] (there is "no statutory basis for fixing an arbitrary limit to the number of prior applications); concurring in dicta, Ricoh Co. Ltd. v. Nashua Corp., 185 F.3d 884, 199 WL 88969,*3 (Fed. Cir. 1999) ("[S]ection 120, governing continuation applications, does not contain any time limit on an applicant seeking broadened claims."). Once a court has determined a statute's clear meaning, there is no room for assertions of "interpretative" rulemaking. See Lechmere, Inc. v. NLRB, 502 U.S. 527, 536-37 (1992) (Once courts "have determined a statute's clear meaning … we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

Equally importantly, there is nothing within the Final Rules "interpreting" the relevant sections of the Patent Act at issue here. Rather, the Rules impose new substantive burdens, requirements and preconditions on patent applicants that diminishes their statutory rights and effects a de facto modification of the applicable statutory provisions.[6]

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[5] As is acknowledged by the USPTO, the Federal Circuit has adopted the decisions of the CCPA as binding precedent. USPTO Mem. Opp. I at p. 17 n. 9; see, South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (*en banc).*

[6] No deference is mandated with respect to rule-making that is contrary to, or inconsistent with, a statute and regulations may not serve to amend or to modify a statute or to add something to the statute that is not already there and must always be consistent with the statutes they are promulgated under. See e.g., Formula v. Schweiker, 572 F.Supp. 862, 866 (D.D.C. 1983); Ruley v. Nevada Bd. Of Prison Commissioners, 628 F.Supp. 108, 111 (D. Nev. 1986).

B. The USPTO'S Final Rules Are Not Consistent With The Patent Act or Other Law

1. 35 U.S.C. §120

Irrespective of the USPTO's protestations to the contrary, Final Rule 78 places real limitations upon continuing application practice. This is easily discernable simply by reviewing the USPTO's own responses to public comments seeking clarification as to under what circumstances the USPTO would grant a petition for a third continuing application. The USPTO responded in nearly every case that it will not grant such a petition, including if "the applicant becomes disabled for a lengthy time during pendency of the application." (See 71 Fed. Reg. at 46769–76 and 77, Col. 2, ¶ 3).

Even the USPTO's very few responses wherein it indicated that it "will likely grant a petition," are phantoms in the dark. (See 72 Fed. Reg. 46773, col. 2, ¶ 2). For example, the USPTO fails to note that its experimentation and newly discovered evidence exception is limited by its assertion that an "[a]pplicant should exercise reasonable foresight to commence any appropriate experimentation early rather than wait until the examiner makes a rejection or finds applicant's arguments unpersuasive." Id. In other words, the USPTO purports to maintain the right to deny even those petitions based on newly generated data on the grounds that the Applicant should have had the foresight to obtain the data beforehand. Further, the USPTO's contention that a petition would likely be granted if "a final rejection contains a new ground of rejection that could not have been anticipated by the applicant" (citing to 72 Fed. Reg. 46774) is a transparent tautology because the USPTO admits that it will not grant such petitions in very many, if any, cases (what "could not have been anticipated" – that the Examiner would cite a manuscript from Mars!). Thus, one is left with a petition (and why a petition would be required in such a case is perplexing) likely being granted when the "Board of Patent Appeals and

Interferences suggests splitting an application subject to an interference." See 72 Fed. Reg. 46776.

The USPTO and its relatively few *amici* simply ignore the clear wording of Section 120 which mandates that the USPTO "**shall**" grant an application for a patent the priority date of a previously filed application if filed before the patenting or abandonment of or termination of proceedings on the first application. See 35 U.S.C. § 120. Moreover, the case law severely limits any power the USPTO has under the doctrine of prosecution laches and, whatever limited power there may be, if any, does not extend to authorizing the USPTO to engage in a *de facto* re-writing of various provisions of the Patent Act.[7]

Here, the USPTO has essentially taken a very limited exception (i.e., prosecution laches) -- intended to apply only in very narrow and extraordinary fact specific circumstances -- and bootstrapped off it to presume in its Final Rules that any applicant seeking to file more than two (2) continuations is guilty of such laches. Along these lines, the USPTO shifts the burden of proof to the applicant to prove otherwise under the Final Rules, although it has no statutory authority to do so.[8] Furthermore, the USPTO adds factual presumptions, which is an indicia of substantive rulemaking. See Paralyzed Vets. of Am. v. Secretary of Veterans Affairs, 308 F.3d 1262, 1266 (Fed. Cir. 2002).

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[7] As stated in Symbol Techs. Inc. v. Lemelson Med. Educ. & Research Found., 277 F.3d 1378, 1385 (Fed. Cir. 2002), the doctrine of prosecution laches should only be "used sparingly least statutory provisions be unjustifiably vitiated … [and] should be applied only in egregious cases of misuse of the statutory patent system." In accord, In re Bogese II, 303 F.3d 1362, 1369 (Fed. Cir. 2002) ("Bogese II") (finding the USPTO's power to reject an application even in a case of *unreasonable* **and** *extreme* delays in prosecution, i.e., prosecution laches, to be limited to situations where the applicant is afforded notice and an opportunity to correct the delay, and implicitly accepting as permitted under the law an applicant who "maintain[s] pendency of an application" to match his claims to a "competitor's products [as they] appear[ed] on the market. Id. at 1369; see also, Kingsdown Medical Consultants Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988) ("[T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application."). The case law is also clear that "the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications" are involved. Ex Parte Hull, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975).

2. 35 U.S.C. § 132

The USPTO offers no legal authority to support its contention that it is not inconsistent with 35 U.S.C. § 132(a) for the USPTO to impose arbitrary limits on RCE filings. Ignoring its own prior interpretation of Section 132 shortly after its enactment that spoke approvingly of an applicant's right to file unlimited RCE filings (see Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,095 (Aug. 16, 2000) – Exhibit 3), the USPTO now futilely tries to distinguish its prior statements regarding RCE practice and Section 132 by asserting that what the USPTO really meant at the time was that it was not going to use its "newly granted" authority under the statute to limit RCE filings. USPTO's Opp. Mem. I at 15.

The USPTO also ignores the fact that the American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1) (1000) makes it clear that Section 132(b) was to apply to all applications filed after June 8, 1995 -- not just one (1) application per family. The USPTO tries to avoid this problem by arguing that Plaintiffs' "all application" argument is based on a mere "unremarkable 'effective date' provision." Id. at 14. There is nothing, however, in the statute reflecting a limitation based on a "patent family." In fact, the USPTO can point to NO patent statute promulgated by Congress that limits an applicant's rights based on a "family" distinction.

[8] The APA does not permit an administrative agency to change the burden of proof unless explicitly permitted by statute. See Heckler v. Campbell, 461 U.S. 458, 468 (1983); accord, Director, Office of Workers Compensation Programs v. Greenwich Collieries, 512 U.S. 267, 271 ("the assignment of the burden of proof is a rule of substantive law").

Aware that it is not able to substantively rebut Dr. Tafas' Section 132 arguments, the USPTO seeks to evade Tafas' assertion that the USPTO's maintenance of "a first action final rejection practice under which the first Office Action in a continuing application, or in the prosecution of a request for continued examination, may be made final" pursuant to MPEP §706.07(b) and 706.07(h) is inconsistent with 35 U.S.C. § 132 by claiming Dr. Tafas' argument is outside the scope of his Amended Complaint dated September 7, 2007 (the "Amended Complaint")(Docket No. 48). (See USPTO Opp. Mem. II at pp. 12-13).

First, Dr. Tafas did "spell out" in his pleading, that: (i) "Section 132 does not empower the Director to deny a continued examination of an application and/or to promulgate regulations having the practical effect of denying an applicant a continued examination of an application" (Amended Complaint, p. 15, ¶ 48); and, (ii) that the "Revised Rules promulgated by the USPTO illegally eviscerate or otherwise alter, … in derogation of the USPTO's limited rulemaking powers under 35 U.S.C. §2 … including, but not limited to, … [i]n restricting the right to file a request for continued examination" ("RCE") to one RCE" (Amended Complaint, p. 18, ¶ 56(j)). Thus, Dr. Tafas' pleading is more than sufficient to meet the liberal notice pleading requirements of Rule 8 of the Federal Rules of Civil Procedure. Even assuming arguendo that was not the case, Dr. Tafas hereby requests and should be granted leave to amend his complaint to amplify his original allegations pursuant to the liberal amendment standard found in Rule 15(a)(2) and 15(b)(1).[9]

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[9] The plain text of Fed. R. Civ. P. 15(b)(1), which governs amending pleadings during and after trial, allows a liberal standard of amendment: "… The court should freely permit an amendment when doing so will aid in presenting the merits and the objecting party fails to satisfy the court that the evidence would prejudice that party's action or defense on the merits …" Fed. R. Civ. P. 15(b)(1). The Fourth Circuit has adhered to FRCP 15(b)(1)'s liberal standard of granting amendments to pleadings. In Medigen of Kentucky, Inc., the Fourth Circuit affirmed the lower court's decision to allow amendments to the complaint just days before trial, finding that "[a]dding the … claim … did not change the substance of the case, did not require additional

The cases relied upon by the USPTO to support its contention that an "as-applied" challenge to "first action final rejection" practice are inappropriate here where the challenge is brought under the APA.[10] (USPTO Opp. Mem. II at 12). Similarly, the USPTO's reliance on case law generated by its own board (*i.e.*, In re Bogese, 22 U.S.P.Q.2d 1821, 1827 (Comm'r Pat. 1991)) is not persuasive. (USPTO Opp. Mem. II at 13, 14). There simply is no weight given to an argument that "it must be assumed that legislators were aware of the practice" when Section 132 was enacted given the state of U.S. Supreme Court case law (see, e.g. Brown v. Gardner, 513 U.S. 115, 122 (1994)("[W]e dispose of the Government's argument that the VA's regulatory interpretation … deserves judicial deference due to its undisturbed endurance for 60 year … there is no other evidence to suggest that Congress was even aware of the VA' interpretative position). The USPTO points to nothing in the history of the Patent Act of 1952 that indicates Congress was aware of the "first office action rejection" practice.[11]

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discovery, and did not prejudice the Commission." Medigen of Kentucky, Inc. v. Public Service Commission of West Virginia, 985 F.2d 164, 168 (4th Cir. 1993). Likewise, in Foxworth, the Court reiterated the liberal standard of amending pleadings found in FRCP 15(b): "The standard for granting leave to amend a civil complaint is very liberal. 'In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant … the leave sought should, as the rules require, be freely given.'" Foxworth v. U.S., 2006 WL 2008722 *1 (E.D.V.A. 2006).

[10] For example, Molins PLC v. Quigg, 837 F.2d 1064 (Fed. Cir. 1988) is inapposite as it dealt solely with whether an applicant that sought mandamus in part as to whether the USPTO's FAFR policy should be rescinded, should have the issue resolved given the justicability rules of the D.C. Circuit, rules that allowed the court to weigh the benefit of review against the resultant hardship to a plaintiff in determining whether to take an issue as ripe. Id at 3-4 ("This case is distinguishable from [a] … facial challenge to the guidelines [which was found] *fit* for judicial review … [Here] we have held that Molin's action is not *presently fit* for judicial review and Molins has failed to demonstrate that delay of review will have a direct and immediate impact upon its primary conduct." Id. at 1068 (emphasis in original)). The USPTO admits plaintiffs in this case "are pursuing a facial challenge of these rules, not an as-applied challenge in a particular case." USPTO Opp. Mem. I at 15.

[11] Section 132(a) requires that "[I]f … the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined." 35 U.S.C. § U.S.C. 132(a). The latter clearly means that the USPTO cannot impose a final rejection in the first action on the merits and

3. 35 U.S.C. § 112

The USPTO maintains that 35 U.S.C. § 112 does not prohibit the USPTO from imposing stringent barriers to the number of claims that may be made in an application. (USPTO Opp. Mem. I at 18). Incongruously, however, the USPTO admits in the record that the "patent statutes … **do not limit** the number of claims (independent or dependent) that may be presented in an application." (A07333 – Exhibit 4). Additionally, the USPTO's position is contrary to In re Wakefield, 422 F.2d 897, 900 (C.C.P.A. 1970) and other courts, which have consistently held that "[A]n applicant should be allowed to determine the necessary number and scope of his claims …." The consistency of this holding has even been acknowledged by the USPTO's own Board of Patent Appeals and Interferences:

> As to the issue of 'undue multiplicity,' **it is well established** that an applicant has the choice of deciding as to the number of claims so long as they are consistent with the disclosure and the requisite filing fees are paid.

Ex Parte John E. Maloney *et al*., 1999 WL 33205694 (Bd. Pat. App. & Interf. 1999) (non-precedential) at *2 . Here, Final Rules 75 and 265 clearly contradict 35 U.S.C. § 112 by not allowing an applicant to file "one or more claims" as permitted by the statute.

In the Application of Don L. Rubinfield, 270 F.2d 391 (C.C.P.A. 1959) does not imply that the USPTO "certainly can require applicants who file more than five independent claims or more than twenty-five total claims to submit additional information to assist in examination without contravening Section 112." (See USPTO Opp. Mem. I at p. 29). Rather,

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that it must instead wait until at least the second action. As further elucidated by Professors Moy and Gorenstein, the history of the practice amply suggests that even before enactment of Section 132, the USPTO understood that such a practice stood on shaky grounds, at best, in fact consistently publishing a defense of the practice as being consistent with its other rules, from its first publication of the Manual of Patent Examining Procedure in 1949 until 1969. William Mitchell *Amicus* Brief at 18 (Docket No. 169).

Rubinfield only dealt with the very narrow question of whether the USPTO's rule to allow only one (1) claim in a *design patent case* was valid under then existing statutes pertaining to design patents. The limitation to one (1) claim in design patent applications was upheld solely because the court deemed the design patent statute to limit presentation to only a single inventive concept (Id. at 396). Of course, in that factual context there was "no useful purpose [that] could be served by the inclusion of more than one claim in a design application or patent." Id. at 395. Rubinfield is further distinguishable because it also depended on a "conflict" test between a rule and a statute, which test was effectively overruled by Adams Fruit Co. v. Barrett, 494 U.S. 638 (1990).

The USPTO also asserts that its Final Rules do not "purport to 'determine the necessary number and scope' of the applicants' claims." (USPTO Opp. Mem. I at p. 19). Whether they "purport" to do so or not is a red herring. The relevant inquiry is whether the Final Rules do have such an effect, which is plainly true because the proposed ESD requirement is nothing more than a poison pill. The USPTO denies this contending that the 5/25-ESD rule imposes minimal regulatory burdens and requires only "simple" showings from applicants: "All [the rules] do is require the submission of an extra document." (See October 31, 2007 Hearing Tr. at 51:17-19). The USPTO's position makes no sense, however, because even taking the USPTO's burden assertions at face value, the reality is that the 5/25-ESD requirement is not only burdensome, but actually an insurmountable barrier for most applicants. (See Tafas Decl., ¶¶ 35, 36 (No. 143); Katznelson *Amicus* Brief at Appendix E (No. 235); Polestar Capital and Norseman Group *Amicus* Brief at 12)(No. 173). Dr. Belzer calculates the 5/25 ESD Rule will consume the full time efforts of between 8,000 and 23,000 patent attorneys. (See Tafas' Opposition to USPTO's Summary Judgment Motion at Exhibit 24)(No.253-254). There are only about 15,000 patent attorneys currently in practice in the United States. Thus, as a practical matter, the 5/25-

ÿESD is likely to bring nearly all other patenting activities to a halt rendering compliance with the 5/25-ESD rule effectively impossible. Furthermore, John Whealen, the USPTO's former solicitor during much of the rule making period, confirmed that the ESD requirement is not a *bona fide* alternative that the USPTO actually intends applicants to exercise (the true intent behind the ESD requirement being to force applicants to abandon property rights by making them too risky and too impractical to exercise):

> If you want all your claims examined up front, you can have it done, but it's going to cost you, you're going to have to do some work, which in the current law of inequitable conduct, nobody's going to want to do.[12]

4. 35 U.S.C. §§ 101, 102, 111, 131 and 151

Using its typical condescending approach to Dr. Tafas, the USPTO flippantly suggests that Dr. Tafas' challenges to the Final Rules beyond those adopted by GSK (which for the most part simply incorporate the arguments Dr. Tafas made in his original motion for preliminary injunction and complaint), "are largely distractions from the core issues in this case," and "uniformly without merit." (See USPTO Opp. Mem. II at p. 1). Nonetheless, the USPTO demonstrates its genuine serious concern about the persuasiveness of Tafas' arguments by proceeding for nearly as many pages as in its other brief (USPTO Opp. Mem. I, the so-called "GSK" Opposition Memo) vainly attempting to refute Tafas' so-called "additional" arguments.

The USPTO urges the Court to "uphold Final Rules 75 and 265 as a reasonable exercise of the USPTO's Section 2(b)(2) authority" and further alleges that 35 U.S.C. §§ 101, 102, 111, 131 and 151 do not preclude the USPTO from requiring an Examination Support Document (ESD) after an artificial threshold number of claims set by the USPTO are exceeded.

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[12] See Duke University Law School, Fifth Annual Hot Topics in Intellectual Property Law Symposium, http://realserver.law.duke.edu/ramgen/spring06/students/02172006a.rm, at time mark 1:02:58. (Exhibit 2)

(Id. at 1-4). As described below, the USPTO's arguments are unsupported and negated by the plain statutory language.

Section 111(a)(1) of the Patent Act mandates that the Director of the USPTO allow for an application to be filed by an applicant "except as otherwise provided in this title." 35 U.S.C. § 111(a)(1). Similarly, Section 101 grants the right to an issued patent "subject to the conditions and requirements of this title." 35 U.S.C. § 101. Section 102 states that "[a] person shall be entitled to a patent unless …" and then delineates various scenarios as exceptions. 35 US.C. § 102. No right is given to the Director to change the requirements for an application, or for an issued patent, outside of the requirements of the Patent Statutes. Section 151 mandates ("shall") that the Director issue a written notice of allowance to the applicant "[i]f it appears that applicant is entitled to a patent under the law." 35 U.S.C. § 151. Section 131 mandates ("shall") that the Director issue a patent if upon examination "it appears that the applicant is entitled to a patent under the law." 35 U.S.C. § 131. No right is given by the patent statutes to permit the Director to fail to give a notice of allowance or to issue a patent if the applicant has satisfied all of the eligibility requirements of the Patent statutes. Id.

The USPTO contends that "by requiring an examination support document ("ESD") when applicants present more than 5/25 claims for examination .. the Office [is not] asking applicants to come forward with a *prima* facie case of patentability, diverging from current practice where the examiner makes a *prima facie* case of unpatentability." (USPTO Opp. Mem. II at p. 2). The USPTO contradicts itself, however, in its own commentary to its Final Rules, which indicate that this is exactly what the USPTO intended to do:

> A general statement that all of the claim limitations are not described in a single reference does not satisfy the requirement of §1.265(a)(4). Section 1.265(a)(4) requires that the examination support document set out with particularity, by reference to one or more specific claim limitations, why the claimed subject matter is not described in the

> references, taken as a whole. The applicant must explain why a person of ordinary skill in the art would not have combined the features disclosed in one reference with the features disclosed in another reference to arrive at claimed subject matter. The applicant must also explain why the claim limitations referenced render the claimed subject matter novel and non-obvious over the cited prior art.

Final Rules, 72 Fed. Reg. at 46742.

The Federal Circuit, and its predecessor court, the Court of Customs and Patent Appeals, have consistently recognized that the patent statutes place the initial burden on the Examiner to demonstrate unpatentability. See, e.g., In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, only then does the burden of coming forward with evidence or argument shifts to the applicant."); In re Piascki , 745 F.2d 1468, 1472 (Fed. Cir. 1984)(same); In re Warner, 379 F.2d 1011, 1916 (CCPA 1967) (decision collecting and analyzing authorities). As stated in In re Warner, the preamble of section 102 makes clear that the initial burden must be on the USPTO:

> We think the precise language of 35 U.S.C. §102 that "(a) person shall be entitled to a patent unless," concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under section 102 and 103 …)

Id. at 1016.

As was well explained by *amicus* Elan Pharmaceutical, the USPTO's representation that the ESD is merely "designed to assist the examiner in determining the patentability of the claimed invention" makes no sense. (Elan Pharmaceutical Brief at p. 14). Specifically, the USPTO's requirement that an applicant search the world and then explain in detail why each and everyone of its claims are patentable under the Patent Act is exactly the USPTO's obligation in the first instance (i.e., the USPTO is required to show unpatentability). Id. The fact that the USPTO has framed its Final Rules so that an ESD is required only upon an applicant exceeding an artificially-set USPTO claim limit, does not change the fact that in these cases the USPTO is shifting the burden (and its job) from the USPTO to the applicant. Shifting the burden of persuasion to prove patentability under Final Rules 1.75(b)(1) and 1.265(a)(1), (4)-(5) are simply contrary to Sections 101, 102, 111, 131 and 151 of the Patent Act.

Similarly, Final Rule 1.78(f)(2) further erects a presumption that claims in two (2) applications are not patentably distinct if the applications meet certain criteria. This *ultra vires* provision effectively eliminates the USPTO's statutory burden to make out a *prima facie* case of unpatentability because the presumption under the Final Rules is that claims in such applications are not patentable for double patenting. The USPTO may not simply unilaterally change its own duties in respect to processing patent applications and transfer them to patent applicants. Cf. In re Longi, 759 F.2d 887, 895-96 (Fed. Cir. 1985) (requiring that the USPTO make out a "*prima facie* case of obviousness" when issuing a double-patenting rejection). As indicated by IPO in its *amicus* brief, the USPTO intended §1.78(f)(2) to shift the responsibility of demonstrating double patenting away from the USPTO and to the applicant:

> Therefore, with the benefit of §1.78(f)(2), double patenting issues could be resolved more expeditiously … thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection.

72 Fed. Reg. 46780.

The USPTO's unilateral shifting of its own statutory obligations onto the applicant is not only *ultra vires*, but also is inconsistent with law because it denies applicants several statutorily-granted rights, including, without limitation, the right under 35 U.S.C. § 133 to have at least thirty (30) days to respond to any rejection or other action, as well as the right of *de novo* reconsideration and review to the USPTO's Board of Patent Appeals and Interferences and to the courts granted pursuant to 35 U.S.C. §§ 134, 141 and 145. As such, a double patenting rejection triggered by the new presumption under Section 1.78(f)(2) improperly denies an applicant its right under the law to *de novo* review on appeal:

> By casing all double-patenting rejections as procedural defects, the USPTO, with one blow, shed its own statutory duty to 'reexamine' rejected applications and divests the Board of Appeals and the Federal Circuit of their statutorily-conferred jurisdiction to review double-patent rejections *de novo*.

IPO *Amicus* Brief at p. 17 (No.171).[13]

5. Patent Cooperation Treaty

Again, 35 U.S.C. § 2(b)(2) does not authorize the USPTO to engage in substantive rulemaking to set the conditions of patentability; to modify the Patent Act; or, to pass regulations that are inconsistent with the law, including U. S. Treaties.[14] Section 706 of the APA specifically authorizes this Court to invalidate regulatory actions that are contrary to law or the Constitution. 5 U.S.C. § 706.

The USPTO's citation to cases failing to reach the issue of whether a regulation violates a treaty, based on a presumption that the treaty was consistent with domestic law, does not help it. Isolated statements in a Congressional record to the effect that a treaty does not change "substantive requirements for obtaining a patent" have no weight in determining whether a set of regulations violate the treaty. The USPTO asserts that it "is improper for Dr. Tafas to suggest that the PCT could prevent the USPTO from altering its procedures." (USPTO Opp.

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[13] Lastly, as noted by *amici* CFPH, this purported burden shifting under the Final Rules not only violates the Patent Act, but also the Administrative Procedure Act, which provides that "[e]xcept where otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. §556(d). (See CFPH Amicus Brief at p. 19; No. 222). As USPTO's examiners issue adjudicatory orders, they are proponents of such orders.

[14] Article VI, Clause 2 of the United States Constitution provides that treatises along with Constitution and Federal Laws are the "supreme Law of the Land." An executive branch agency cannot on its own volition violate a treaty entered into by the United States. Id.

Mem. II at 39). Dr. Tafas asserts, however, that there is nothing improper in requiring the USPTO to follow the U.S. Constitution.

In accord with both subsections of Article 4G of the Patent Cooperation Treaty (PCT), an applicant has the absolute right to divide a patent application to preserve the benefit of the priority date of the initial filing, whether based on an examiner's finding, or the applicant's own initiative. As noted by *amicus* Federation Internationale Des Conseils, while subsection (2) allows signatory nations to "determine the conditions under which such division shall be authorized," the European Patent Office itself has found that it confers no authority allowing signatories to restrict the number of divisional applications that an applicant can seek to file. *Cf.* Board of Appeals of the European Patent Office Case No. J 0011/91, at para. 3.1.1 (Aug. 1992) (Exh. B to their *amici* brief)(No.140).

Furthermore as the ESD requirement is not among the exceptions to Article 27 of the PCT identified in Rule 51*bis*.1 PCT, imposition of the ESD procedure on patent applicants filing under the PCT is prohibited under Article 27 PCT. The USPTO's argument that the list set forth in PCT Rule 51*bis*.1 was not meant to be exhaustive, given the use of the phrase "in particular" in PCT Rule 51*bis*.1 is not persuasive given that the USPTO's ESD requirement parallels none of the exceptions to Article 27.[15] Further, the USPTO's recitation to Rule 51*bis*.1 for the statement that "national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by law" again misses the point. (USPTO Opp. Mem. II at pp. 41). While the provision allows for an office to require evidence of patentability to be supplied by an applicant once a *prima facie* case of unpatentability has been made by a signatory, it is not designed to require that an applicant prove patentability by doing a

[15] The USPTO's recitation to proposed amendments to the PCT in footnote 27 of USPTO's Opp. Mem. II p. 40 also simply carries no weight.

worldwide search of the literature available, and then arguing patentability on each point, as is required by the ESD requirements of the Final Rules.[16]

The USPTO attempts to dodge Dr. Tafas' assertion that the Final Rules violate the Patent Cooperation Treaty ("PCT") by raising an argument that Tafas did not specifically mention the PCT in his Amended Complaint. Again, the Amended Complaint adequately put the USPTO on notice, consistent with FRCP 8, that Dr. Tafas is claiming that the Final Rules are contrary to law (which, of course, is inclusive of treaties). Moreover, if deemed necessary, Dr. Tafas begs leave to amend his complaint and/or to conform it to the proof as authorized by FRCP 15(a) and (b). (See, infra, p. 11-12 n. 9).

6. 35 U.S.C. § 121

35 U.S.C. §121 was enacted by Congress to protect applicants against USPTO reversals in determining whether claims are patentably distinct. See, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 361 (Fed. Cir. 1986) (the statute "effects a form of estoppel that shields the applicant from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent"). Section 121 is plain on its face that its drafters understood that there was another type of divisional application, one that was not a result of a restriction requirement, available to applicants. With this knowledge, Congress specifically tailored protection to those "issuing on an application with respect to which a requirement for restriction … has been made." Id. That is, the other type of divisional, known in the art as a "voluntary divisional," was not to be given the special protection against

[16] Additional supporting arguments as to how the Final Rules violate the PCT are found in the *amici* briefs of Federation International (pp. 3–4)(No. 140) and Robert Lelkes (pp. 2–8)(No. 225).

"patentably distinct" reversals as one where there was "a requirement for restriction." The Final Rules improperly restrict applicants' rights to file the other type of divisional under Section 121.

Furthermore, Section 1.78(f)(2) of the Final Rules circumvents the protection provided to applicants filing a divisional application pursuant to a restriction requirement, by applying a presumption of patentably indistinct claims between a divisional application which will share the same disclosure, filing date, and presumably inventorship and ownership, with its respective parent application. By allowing the USPTO to presume that the claims of a divisional application are patentably indistinct from its parent applications, the Final Rules overcome the very basis for the passage of 35 U.S.C. § 121. Under the Final Rules, an applicant filing a divisional application must demonstrate that its claims are patentably indistinct even to merit the protection of 35 U.S.C. § 121. This is simply not permissible under the statute.

7. 35 U.S.C. § 122

First, the USPTO seeks to duck Tafas' arguments concerning the *ultra vires* nature of the Final Rules in respect of 35 U.S.C. § 122 by arguing that they are outside the scope of the Complaint. (USPTO Opp. Mem. II at pp. 5-6). Again, Dr. Tafas' complaint adequately apprised the USPTO of Dr. Tafas' position and, even if it did not, any technical defect should be curable by amendment. (See Amended Complaint, p. 18, ¶ 56(h)).

Second, the USPTO's standing argument again shows a failure of the USPTO to appreciate the entire *facial* basis of the APA challenge in front of this Court. Instead of dealing with Tafas' assertion that provisions of the Final Rules are inconsistent with 35 U.S.C. § 122, the USPTO tries to avoid squarely addressing the problem by linguistic twists such as stating that the problem Tafas points out is an "unlikely hypothetical," or merely "speculation." The USPTO suggests that an applicant has an available alternative "to keep certain information about the second application out of the publicly-available file by filing a 'petition to expunge.'" (USPTO

Opp. Mem. II at p. 6). Even assuming arguendo that this "alternative" somehow could operate to partially mitigate the loss of statutory rights, the Final Rules are still inconsistent with law because Section 122 requires the "Patent and Trademark Office" -- NOT the applicant -- to keep in confidence such information pertaining to patent applications. See Irons v. Diamond, 670 F.2d 265, 267-68 (D.C. Cir. 1981).

8. 35 U.S.C. §§ 41, 112

The USPTO pays little attention to Dr. Tafas' argument that Final Rule 1.75(b)(2) impermissibly alters fees payable by an applicant by engrafting the limitation that "[a] claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee calculation purposes" to the statutory definition of dependent and multiple dependent claims found in 35 U.S.C. §112. (See USPTO Opp. Mem. II at pp. 10-12).

The USPTO attempts to divert attention from its failure to address whether the USPTO has the right to change statutorily set fees payable by applicants for a "product-by-process" claim by instead seeking to talk about dependent claims themselves. Id. at 11. The fact is, and as the USPTO well knows, "product-by-process claims" have been interpreted by the Federal Circuit in two (2) very distinct manners. First, as a claim to a product made by any process that matches the product produced by following the specified process, and alternatively, a claim to a product only made by following the steps of that particular process. Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1580 (Fed. Cir. 1991); Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992). In any case, "product-by-process claims" have always been treated as dependent claims by the USPTO, as they should be, as they meet the definition of a dependent claim pursuant to 35 U.S.C. §112.

Here, Final Rule 1.75(b)(2) is inconsistent with law because it converts "product-by-process" claims into **independent** claims for fee purposes even though they "contain a reference to a claim previously set forth [which] … specif[ies] a further limitation of the subject matter claimed." (See Tafas Mem. In Support of Summary Judgment dated December 20, 2007 at pp. 12 and Tafas Mem. In Opp. To Def. Summary Judgment Motion dated January 22, 2007 at pp. 23). The USPTO's citation to IPXL Holdings, 430 F.3d 1377 (Fed. Cir. 2005) is inapposite because in that case the court found a single patent claim covering both an apparatus and the method of using that apparatus to be invalid for indefiniteness – and not because the claim was directed "to multiple statutory classes" as argued by the USPTO. Id. at 1384.

The USPTO cannot dodge through smoke and mirrors the indisputable fact that "product-by-process" claims must be treated as dependent claims. In its Final Rules, the USPTO has effectively modified the statutory definition of a dependent claim in Section 112 and now treats "product-by-process" claims as independent claims for fee purposes. This is inconsistent with 35 U.S.C. §§ 41 and 112.

The USPTO mischaracterizes Dr. Tafas' argument concerning "multiple dependent" claims. Dr. Tafas is not claiming that the USPTO violates the fee statute (Section 41 of the Patent Act) with respect to "multiple dependent" claims. (See contra USPTO Opp. Mem. II at 11-12). Instead, Dr. Tafas contends that the USPTO does not have the right to alter statutory definitions in any manner that cause additional consequences to an applicant unforeseen by Congress. Here, Final Rule 1.75(b)(4) redefines multiple dependent claims by counting them for purposes of its new 5/25 claims rule as the number of claims to which direct reference is made. Clearly, this was not part of the Congressional definition of multiple dependent claim found at Section 112. (See Tafas Mem. in Support of Summary Judgment dated December 20, 2007 at pp. 13 and Tafas Mem. in Opp. To Def. Summary Judgment Motion dated January 22, 2007 at pp. 24).

9. 35 U.S.C. §§ 200-212

The USPTO fails to address Dr. Tafas' argument that the administrative record is devoid of anything reflecting that the USPTO affirmatively considered the impact of its regulations upon the objectives of the Bayh-Dole Act (35 U.S.C. § 200 *et seq*.) and thus failed to under a necessary step in formulating the Final Rules. Instead, the USPTO tries to deflect the Court's attention away from the above issue arguing only that Dr. Tafas did not show that the "Final Rules violate any actual rights, requirements, or obligations of the Bayh-Dole Act." (USPTO Opp. Mem. II at p. 9). Final Rule 1.78(d)(B) does, however, interfere with the commercialization of inventions developed under the Bayh-Dole Act by dictating that an applicant withdraw a species claims that could be rejoined and to exhaust prosecution of the applicant's generic claim in its initial application and its continuation/continuation-in-part applications, including exhaustion of any available appeal, before a divisional application directed to a non-elected species may be filed. (See Tafas Summary Judgment Mem. at p. 20)(No. 135). Irrespective of the USPTO's comments to the contrary, there is no such restriction or limitation presently imposed under the Patent Act.

C. The Final Rules Are a Result Of Arbitrary And Capricious Rulemaking

The USPTO maintains that Tafas' "arbitrary and capricious" arguments rely on "extra-record" evidence and, therefore, should be ignored.[17] (USPTO Opp. Mem. II at p. 15).

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[17] The USPTO fails to recognize that much of the "evidence" Dr. Tafas relies on has already been entered into the court record in connection with the various motions brought by the USPTO against him, evidence that was not objected to at the time of its submission to this court. Furthermore, the USPTO confuses the concept of "documents in the record" with their own "produced administrative record" (as they have in the past attempted to confuse the Court by failing to make the distinction between their "produced administrative record," and their "compiled administrative record" – i.e., the actual administrative record which was later purged of materials asserted by the USPTO to be protected by a privilege).

The USPTO ignores Federal Rules of Evidence 402 and 607, which allow the admissibility of relevant evidence and impeachment of the credibility of the witness (which in this case is the USPTO). Tafas is aware of no exception in the Federal Rules of Evidence exempting APA cases. Even assuming *arguendo* that Tafas is not permitted to use extra-record evidence to supplement the record *per se*, this does not by extension mean that Tafas should be precluded from citing to matter outside the record to **impeach** the credibility or completeness of the record as part of demonstrating "arbitrary and capricious" rule making. Under the USPTO's twisted logic, if the USPTO had asserted in its Notice of Rule Making that 2+2 = 5 or that "the earth was flat" rather than round, Dr. Tafas would be forced to simply accept these propositions and would be precluded from introducing testimony from mathematicians and scientists to refute these absurd and patently wrong propositions. Of course, Dr. Tafas would have every right to utilize so called extra record materials to critique the USPTO's record under those circumstances (which is exactly the same type of proper impeachment being engaged in here).

The USPTO urges the Court to turn a blind eye to Tafas' demonstration of serious disconnects (which the USPTO references as "inconsistencies") between what the USPTO told the public about the effects of proposed rules and what the USPTO was telling the Office of Management and Budget ("OMB") during the notice and comment period.

First, in its recent discovery ruling the Court has already rejected the USPTO's argument that the OMB proceedings are irrelevant to the USPTO's rulemaking. Tafas v. Dudas, 2008 WL 112043, at p 8 (Jan. 9, 2008)("Tafas II")

Second, the USPTO ignores the fact that the inconsistencies demonstrated by Dr. Tafas relate to specific conflicting statements pertaining to provisions of the Final Rules and Proposed Rules. This is clearly relevant and admissible evidence regardless of whether the inconsistent statements were made in different forums.

The USPTO contended earlier in this case that "Tafas' statistical arguments about ESD use; … his disagreement with the USPTO over whether people will be deterred from submitting ESDs due to fears of inequitable conduct; … his dispute over the USPTO's understanding of the term 'rework'; … [and] his arguments about the USPTO's appeal statistics are all reasons he may choose to argue at summary judgment that the Final Rules are arbitrary and capricious." (Def. Omnibus Mem. In Opposition to Plaintiffs' Req. for Discovery dated Nov. 26, 2007 at p. 24). Now the USPTO has changed its tune and contends that all of these factors, and Tafas' supporting evidence, are simply irrelevant to the matter of arbitrary and capriciousness. (USPTO's Opp. Mem. II at p. 15). Given its change of position, the USPTO should be estopped from challenging Dr. Tafas' listing of contradictory behavior by the USPTO to the public, this Court, and the OMB (which the USPTO needed to pass off on many of its USPTO's initiatives necessary for implementation of the Final Rules).

Throughout this case and as part of the summary judgment proceedings, Dr. Tafas has identified numerous USPTO statements that its Final Rules would have "little impact" on patent applicants. While the USPTO now purports to controvert this claiming that Dr. Tafas "fails to specify any such comments" – the evidence to the contrary is indisputable.

First, the USPTO ignores the many representative USPTO comments on this issue that are part of the administrative record:

> The changes in this final rule do not impact applicants' ability to protect improvements to the invention disclosed in a prior-filed application.

72 Fed. Reg. 46748.

> These final rule requirements for seeking a third or subsequent continuation or continuation-in-part application will not impact the vast majority of the applications.

72 Fed. Reg. 46765.

Along the same lines, the USPTO erroneously stated to the OMB that it did not expect its new rules to have any substantial adverse impacts on patent applications. For example:

(a) The USPTO represented to the OMB that it expected ESDs in only 5,000 cases, however, it did not tell OMB that approximately 143,000 applications exceed 5/25 claims every year;

(b) The USPTO misrepresented to the OMB in its September 26, 2007 ICR submission that it received "no comments" from the public in regard to the time to provide information under its ESD requirements. OMB instructions in Form 83-I requires agency reporting on public inputs under two input categories. The USPTO reported having received no public comments in response to a specific 60-day solicitation notice ***and*** in contacts with patent user organizations apart from, and outside of, the notice and comment period. (See Exhibit 5). As to the former category, it is true that the USPTO received no comments in response to its ICR submission and the reason is evident – the comment period designated by the USPTO closed a year and two months before the September 26, 2007 ICR disclosed for the first time estimated paperwork burdens associated with the Final Rules. That is, after the Final Rules were published, the USPTO inappropriately designated a May 30, 2006 notice (which contained no information collection items related to the Final Rules) as initializing the 60-day public comment period for the September 26, 2007 ICR. As to the latter category, Exhibit 3 shows that the USPTO specifically stated that there were "no comments or concerns" under this category as well. This was simply not true. Under the second input category, the USPTO was obligated to report to the OMB relevant "comments or concerns expressed by organizations" such as AIPLA, at ***any time*** including during the Town-Hall meetings of 2006 and during the written comment period in the proceeding that led to the Final Rules. The USPTO kenw several parties had offered critical and relevant comments including the AIPLA, complaining about the excessive paperwork burdens associated with ESD's. (See AIPLA comments to Proposed Claims Rules, Exhibit 6, at A00679-A00680).

Moreover, the USPTO also erroneously states that Dr. Tafas is unable to point to any public statements by the USPTO that its Final Rules impose no limits on the number of continuation applications. Numerous such statements by the USPTO are found, inter alia, within the administrative record and in various court pleadings in this case:

> The Final rule … does not place any absolute limit on the number of continuing applications and request for continued examination.

72 Fed. Reg. 46757.

> [T]here is no absolute limit on the number of continuing applications an applicant must file…

Def. Opposition to Plaintiff's Motion for TRO and Preliminary Injunction, p. 26.

> Therefore, the $400 petition fee and the showing requirement will impact only a small minority of applicants.

72 Fed. Reg. 46776.

There is also compelling evidence (that Dr. Tafas had been hopeful to further develop through discovery) that the USPTO was, in fact, aware that its Final Rules would impose significant hardships on applicants and deter them from exercising certain rights afforded under the Patent Act. For example, the fact that the USPTO told the OMB it expected only 1,000 petitions out of 11,326 applications (based on FY 2006 numbers) that would have been affected by the Final Rules (i.e., the USPTO was anticipating that prospectively more than 90% of applicants who might have otherwise have previously filed more than two (2) continuations in years past would not file a petition under the Final Rules) belies the USPTO's suggestion that the petition requirement would merely alter the *manner* by which applicants would exercise the right. Clearly, the USPTO was hopeful that its Final Rules would deter over 90% of applicants who might otherwise have filed a third continuation filing from doing so in the future under the new Final Rules.

The USPTO also offers no meaningful or serious response to Tafas' contention that the USPTO made contradictory and misleading statements about the effect of its continuation/claims rules when the USPTO stated that any negative effect would be ameliorated by a rapidly decreasing inventory in appeals, while at the same time indicating to Congress in its USPTO Budget (p. 32, note 27) that it expected appeals to increase by approximately one-third.

The USPTO simply tries to deflect this incongruity by urging the Court to look at its "pre-appeal brief conference."

Similarly, the USPTO's suggestion that the flagrant contradictions between the USPTO's representations to the OMB indicating a substantial economic effect to the public if the Proposed Rules were implemented, while asserting to the public in the USPTO's EO 12866 Regulatory Review that the Proposed Rules were not economically substantial, is not inconsequential simply because the contradiction applies to the Proposed Rules.[18] The Proposed Rules are the only rules that were made subject to the USPTO's *ersatz* notice and comment period and, if the public was aware of the USPTO's conflicting positions as to substantial economic effects, it is only reasonable to believe that this could have had a material impact on the volume and type of comments received.

Likewise, the USPTO's manipulation of data in 2007 to decrease its reported regulatory burden associated with the new rules -- by splitting forms -- is not inconsequential and presumably aided the USPTO in its quest for OMB approval for implementation of its Final Rules. It is frightening that the USPTO even has the temerity to suggest that the USPTO's inconsistent statements to different government agencies and the public concerning the effect of proposed rules, which will have a dramatic impact on future innovation, are somehow okay.

The USPTO also does not really address Dr. Tafas' argument that the USPTO failed to consider the benefits of current patent strategies employing continuation practice as weighed against any perceived abuse of the system. It is well established that courts often overturn rules that fail to sufficiently calculate costs or benefits when such analysis is necessary. See Morall v. DEA, 412 F,3d 165, 167 (D.C. Cir. 2005) (overturning a regulation as arbitrary and capricious because the rule making was "stunningly one-sided in focus").

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[18] Of course, the USPTO's suggestion that its inconsistent statements concerning the Proposed Rules have nothing to do with the Final Rules is simply untenable and illogical. The Proposed Rules were opened to the public for comment during the USPTO's *ersatz* Notice and Comment period. The Proposed Rules are the rules that the USPTO maintains the Final Rules sprung from as a logical outgrowth (see discussion, infra). The Proposed Rules (from which the Final Rules sprung) are necessarily highly relevant to adjudicating whether the Final Rules are arbitrary and capricious.

Finally, Dr. Tafas also did not assert that "Under Secretary Dudas failed to cite specific numbers in his Congressional" testimony as the USPTO suggests, but rather Dr. Tafas' position is that the figures Mr. Dudas provided to Congress were not backed up by the numbers the USPTO provided in its produced administrative record.

D. The Final Rules Are Not A Logical Outgrowth Of The Proposed Rules

As a threshold matter, the USPTO asserts that the notice and comment requirement of the APA, as well as the logical outgrowth doctrine, are inapplicable here because the Final Rules are procedural rather than substantive." (USPTO Opp. Mem. at p. 23). Again, Tafas contends that the rules are substantive and the USPTO was required to utilize a proper notice and comment period. The USPTO's *ersatz* notice and comment period cannot help it, as the public would understand from the USPTO's assertions that the rules were procedural and not subject to the APA,[19] that any comments they provided to the USPTO may well have been superfluous and not necessarily subject to the same due consideration required under 5 U.S.C. § 553(c).

The remainder of the USPTO's arguments on logical outgrowth depends on the changes in the Final Rules being "reasonably foreseeable." (USPTO Opp. Mem. II at p. 23).

[19] See 72 Fed. Req. 46830 – "these rule changes involve interpretative rules, or rules of agency, practice and procedure … exempt from the Administrative Procedure Act's notice and comment requirement,"; see also 71 Fed. Reg. 50 referencing that the Proposed Rules were to "revise the rules of practice."

Here, the substantial changes made to the Final Rules were not reasonably foreseeable. (See Tafas Mem. In Support of Summary Judgment dated December 20, 2007 at pp. 30-31 (No. 135).

Again, under the Proposed Rules, an ESD was only to be required in cases where an applicant sought examination of more than ten (10) claims. In the Final Rules, this subsequently morphed into a 5/25 hard and fast rule, wherein the number of total claims could suddenly evoke an ESD, and wherein the absolute number of independent claims an applicant could have searched without evoking an ESD was cut in half. Dr. Tafas submits that there was no way one could also reasonably envision the following changes made in the Final Rules:

(i) that the USPTO would attempt to expand its power to reach the requirements for patentability by adding a requirement under Final Rule 1.104 to require Examiners to take into consideration "other requirements," such as the MPEP, in making determinations of patentability;

(ii) the requirement under New Rule 1.704 allowing for a patent term adjustment if an application contained more than 5/25 claims and no ESD, if the applicant failed to file an ESD until after four (4) months after the filing date of the application.

E. The Final Rules Are Retroactive And Result In An Unconstitutional Taking Under the Fifth Amendment and Due Process Clause of the Constitution

The USPTO's conclusory statements in its Federal Register publication of its Final Rules do not satisfy its requirement under the APA to consider this important issue:

> This rule making will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

72 Fed. Reg. 46,834.

As set forth in Landgraf v. USI film Prods., 511 U.S. 244, 269 (1994), retroactivity is seen when the regulation or statute (1) "would impair rights a party possessed when he acted" or (2) "impose new duties with respect to transactions already completed." These rights need not be completely vested as suggested by the USPTO. (USPTO Opp. Mem. I at p. 32). Quite to the contrary, rights in patent applications also derive from the *quid pro quo* involved in a patent applicant foregoing trade secret protection for patent protection. (See Tafas Mem. In Supp of Preliminary Injunction dated August 23, 2007 at pp. 26-27. Ruckelhaus v. Monsanto Co., 467 U.S. 986 (1984) makes clear that intellectual property is protected under the Takings Clause. In Penn Central Transportation Co. v. City of New York, 483 U.S. 104, 124 (1978), the Supreme Court defined the relevant factors n determining whether a taking has occurred. GSK agrees with Tafas's analysis, that "in retroactively denying … the right to file multiple continuation applications, Defendants have effected a taking that satisfies all three (3) factors" of Penn Central. (See Tafas' Mem. of Law in Support of Motion for Preliminary Injunction, August 22, 2007, p. 26).

Here, the retroactive application of the Final Rules does effect a taking of property rights (both without due process of law and otherwise).[20]

F. The USPTO Has Violated Article I, Section 8 Of The U.S. Constitution In The Promulgation Of The Final Rules

Once again, the USPTO urges the Court not to consider Dr. Tafas's argument that the Final Rules implicate a separation of powers issue, that is, his argument that Article I, Section 8 of the U.S. Constitution grants Congress, **NOT** the executive branch, the power to enact substantive rules of patent law. Again, the USPTO asserts that something more than notice pleading is necessary in a complaint filed against the USPTO. And again, Dr. Tafas points to a provision in his complaint showing the issue was raised: "The APA prohibits agency action which is "contrary to constitutional right, power, privilege or immunity." Further he notes his own preliminary injunction motion wherein he explains: "The Constitution of the United States gives Congress the power to enact law relating to patents …governmental agencies must act within constitutional parameters … [a] reviewing court must hold unlawful and set aside any agency actions not in accordance with the law … whether the law is statutory-based or constitutional based." (Tafas Mem. in Support of Motion for Preliminary Injunction, pp. 22–23).

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[20] The USPTO's argument that Dr. Tafas' takings or separation of powers arguments are somehow outside the scope of his complaint is meritless. The takings claim is clearly posited on the face of the complaint (Amended Complaint, Docket #14) and the separation of powers argument is implicit, if not explicit. Even assuming *arguendo* that there is a requirement for Dr. Tafas to separately enunciate his takings theory into two (2) parts (i.e., a taking involving a due process violation (as pled) and a straight taking), Tafas should be granted leave to amend pursuant Rules 15(a) and 15(b) of the Federal Rules of Civil Procedure.

The USPTO argues that Congress has given the USPTO substantive rulemaking authority. The problem is it can not point to any case or statute that says that Congress has indeed given it this authority. In fact, it even attempts to overcome the clear statement of the Federal Circuit in Merck & Co., Inc. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996) that the USPTO does not have substantive rulemaking authority, by urging the court to look at such statement as mere dicta. Def's. Second Opposition Brief at 21. Clearly, if Congress has not delegated powers to the USPTO granted by the Constitution solely to the legislative branch, the USPTO, as part of the executive branch, violates the separation of powers doctrine.

In respect of Dr. Tafas's further contention that the USPTO violated the Patent Clause because it failed to take into account the effect of its Final Rules on the advancement of the "promotion of science and useful arts," the USPTO urges the Court to ignore his argument based on the failure of the Supreme Court to specifically deal with the issue in Eldred v. Ashcroft, 537 U.S. 186 (2002) (although it makes several statements suggesting the Supreme Court ruled that the preamble did not create an enforceable right, footnote 19 of its brief elucidates the truth "The Eldred Court did not ultimately have to decide whether the preamble created an enforceable limitation."). Dr. Tafas disagrees that issues that have not yet been adjudicated by the Supreme Court, should be ignored in litigation. He also disagrees that the USPTO in its Federal Register notice provided a rational basis "for the conclusion that the Final Rules 'promote the progress of science and the useful arts.'" (Def. Opp. Mem. II at 22).

Dr. Tafas notes the consistently stated purpose of the USPTO in passing its Final Rules, that is to reduce its backlog:

> In view of the need for a better focused and effective examination process to reduce the large and growing backlog of unexamined applications while maintaining or improving the quality of issued patents…

72 Fed. Reg. 46717.

> The changes in this final rule will permit the Office to apply the patent examining resources otherwise consumed by these applications to the examination of new applications and thereby reduce the backlog of unexamined applications.

72 Fed. Reg. 46719.

> As a result, the Office is modifying continued examination practice in this final rule to address the backlog of unexamined new applications.

72 Fed. Reg. 46753.

Irrespective of the USPTO's comments to the contrary, Dr. Tafas asserts that resolving an administrative backlog, without taking into account the damage to the promotion of sciences and the useful arts, and without looking at actual data, violates the obligations the USPTO has under the Patent Clause. If a backlog of work is enough of a reason for the promotion of science and the useful arts, then Dr. Tafas suggests everyone at the USPTO take a very long vacation, and then change the rules when they come back to rid themselves of an even larger backlog!

G. The Final Rules are Invalid in Not Providing Sufficient Notice to Applicants of How to Comply With An ESD

Dr. Tafas adds to the arguments made in his summary judgment motion with respect to the vagueness problem associated with the ESD requirement by referencing the briefs of *amici* Monsanto Company (pp. 11–12) and Pharma (pp. 15–18). Dr. Tafas repeats his assertion that whether or not a constitutional void-for-vagueness challenge is appropriate with respect to such regulations,[21] that the degree of vagueness of the ESD requirements provides ample evidence of the arbitrary and capricious nature of the Final Rules. Dr. Tafas also points to his own declaration attached to his summary judgment motion, wherein he notes even search companies familiar with the Office's accelerated examination procedure were unwilling to certify to him that their search was ESD compliant as they could not make heads-or-tails of what was required. (See Tafas Declaration, p. 12 at ¶ 36).

H. The Final Rules Were Promulgated In Violation Of The Regulatory Flexibility Act

Clearly recognizing USPTO's weak position in justifying its Regulatory Flexibility Act Certification of no significant economic impact on a substantial number of small entities (*i.e.*, no "SEISNE"), the USPTO spends nearly one quarter of its Second Opposition Brief attempting to justify it.

The USPTO attempts by smoke and mirrors to convince the Court that an unreasonable basis for a certification of no SEISNE is "ok," under the Regulatory Flexibility Act (RFA) because it is "merely a procedural statute". A flawed certification of SEISNE is not "ok," and a certification based on a finding of no SEISNE cannot be based on a myriad of suppositions that simply blind the agency to the rules' impacts on small entities See e.g., North Carolina Fisheries Ass'n v. Daley, 27 F.Supp.2d 650, 654-55 (E.D.Va. 1998). The RFA places the affirmative duty on the regulating agency to prudently calculate its rule's economic impact on small businesses. See North Carolina Fisheries Ass'n v. Daley, 16 F. Supp. 2d 647, 653 (E.D. Va. 1997).

Congress added the RFA's judicial review provisions when it enacted SBREFA in 1996. In doing so Congress recognized "that agencies have given lip service at best to [the]

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[21] Tafas agrees with GSK that it is appropriate.

RFA," and so provided small entities the legal means to hold agencies accountable under the law. *See* 142 CONG. REC. S3242, S3245 (daily ed., Mar. 29, 1996). The Department of Commerce's RFA guidelines, state:

> Ultimately, the question the RFA analysis needs to answer is whether in the short- and medium-term, the costs (or reduction in revenues) imposed by the regulation can be absorbed by the firm (due to higher than average profitability) or passed on to its customers. If these costs (or reductions in revenues) cannot be absorbed so that either profits are reduced significantly or the solvency (ability to meet long term debt payments) of a substantial number of small entities is clearly threatened, then the impact of the rule is significant and the Department should not certify.

U.S. Department of Commerce, "Guidelines for Proper Consideration of Small Entities In Agency Rule Making," ("DOC Guide") available at http: //www.ogc.doc.gov/ogc/legreg /zregs/guidelines.htm (last visited Dec. 19, 2007).[22] Courts have frequently overturned flawed certifications of no SEISNE. See Southern Offshore Fishing Ass'n ., Daley, 995 F. Supp. 1411, 1436 (M.D. Fla. 1998) (invalidating and remanding flawed RFA "no significant impact certification"); see also North Carolina Fisheries Ass'n v. Daley, 16 F. Supp. 2d 647, 658 (E.D. Va. 1997) (strongly criticizing an agency for persisting in supporting flawed RFA analyses and imposing injunctive relief).

It should be noted by the Court that the case law makes clear that there is no deference to be granted to an agency's certification of no SEISNE as the issue is not within a agency's particular expertise. See Airlines Traffic Offices, Inc. v. Department of Defense, 87 F.3d 1356, 1361 (D.C. Cir. 1996).

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[22] In the present case, Defendants were required to perform RFA analyses because: (1) the Final Rule was a "rule," as the term is defined in 5 U.S.C. § 601(2), in that it meets the definition of legislative or substantive rule as defined by the courts of this Circuit, as shown above; (2) Section 553(b) of the APA "required" the USPTO to publish a general notice of proposed rulemaking for the Rules (*see* 5 U.S.C. §§ 603(a) & 604(a)), because the Rules represent and contain a substantive or legislative rule as that term is used in APA jurisprudence; and (3) the

The USPTO's certification obscures the rules' impacts on small entities by inflating the universe and ignoring the disproportionate impacts on such businesses. The USPTO engages in the same type of artifice that Judge Doumar found "amounts to willful blindness" under very similar circumstances. North Carolina Fisheries Ass'n v. Daley, 27 F. Supp. 2d 650, 659 (E.D. Va. 1998). In that case, this Court found the agency had diluted its analysis of the rule's impacts by using the total number of permitted fishing vessels, rather than the subset of vessels that depended on the regulated fishery. Id.

Even if the a certification of no SEISNE was all the USPTO needed to issue, as a fundamental matter under the APA, any such certification must have a rational basis in the administrative record. Agency conclusions lacking such a rational administrative record basis cannot stand. See, e.g., Atlantic Fish Spotters Ass'n v. Daley, 8 F. Supp.2d 113, 116 (D. Mass. 1998). Clearly as set forth in the Fenili affidavit, and in the amici briefs of Dr. Katznelson, and Polestar Capital and Norseman Group (particularly in the declaration of Dr. Richard Belzer), the USPTO's assumptions were not reasonable. For example, Dr. Tafas entirely disagrees with the USPTO that its estimate of average gross revenue for a small entity affected by the rules of $75,000 was not unlike the situation in South Offshore Fishing Association Daley, 995 F.Supp. 1411 (M.D.Fla. 1998), wherein the court found no rational basis for the average gross revenue of a shark fisher. The exact situation exists here. The selection of $75,000 for such hypothetical small entity is simply a flight of fancy, not as the USPTO asserts based on existing data supported by the record. (USPTO Opp. Mem. II. at 32). Dr. Tafas further entirely disagrees with the USPTO that it can overcome CLEAR failures in its no SEISNE June 29, 2007 RFA Certification Analysis by citation to isolated statements in its administrative record. The

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Rules effect "a substantive change in a prior rule." U.S. Telecom Ass'n v. F.C.C., 400 F.3d 29, 30 (D.C. Cir. 2005). Thus the USPTO must urge that its rules were procedural.

USPTO attempts to get around the fact that its Certification failed to take account the costs associated with rebutting the presumption regarding "patentably distinct claims' by references to statements it made outside of the ICF Certification). Additionally, the USPTO's suggestion of the amortization of a patent over 20 years is simply without merit.[23] The USPTO's response to Dr. Tafas's remark that the USPTO failed to consider the additional costs of preparing more applications in order to stay within the 5/25 rule, simply does not pass a "face test." The fact that some applicants who file excess claims also file numerous applications simply has NOTHING to do with whether the USPTO should have considered the effect of its rules on causing applicants in general to file more patent applications.

Despite Dr. Tafas' memorandum, Dr. Fenili's declaration, Dr. Belzer's declaration, and the Dr. Katznelson's brief, the USPTO asserts that Dr. Tafas was "[u]nable to directly attack the Office's impact data." (USPTO Opp. Mem. II at 36). However, each of these declarations attacks the Office's impact data and finds it totally without merit.

The USPTO's attempt to knock Dr. Fenili's declaration is simply loquacious rhetoric without any meat. There is nothing misleading about Dr. Fenili's data, Dr. Belzer's data, nor Dr. Katznelson's data. Maybe the USPTO with the type of care it has shown in its review of its own ICF certification (such that repeated statements of a patent having a twenty year term were not corrected) could be misled from Dr. Fenili's chart into "assum[ing], mistakenly, that both the numerator and denominator have been adjusted to remove small entities," but not most careful readers of the document.

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[23] The life span of a patent is significantly shorter than twenty years as the patent term is adjudged from the filing date of an application, not its issue date. USPTO Opp. Mem. II at at 34).

There simply is NO basis for the USPTO's criticisms. The USPTO even fails to note to the Court that the chart they complain of is based on the USPTO's own data, which Dr. Fenili finds wholly unsupportable. Recognizing the serious injury it may face if the Court actually looks carefully at the declaration of Dr. Fenili, along with the declarations of Dr. Belzer and brief of Dr. Katznelson, the USPTO not only urges the Court to ignore them as outside of the record, but resorts to name calling, questioning the "expert[ise]" of Dr. Fenili. (USPTO Opp, Mem. II at 38. When one has to resort to slurs, the assailant's position is typically very weak.

I. The USPTO's Assertions of Continuation Practice Abuse Is Not Supported By The Evidence

The USPTO fails to address in any manner Dr. Tafas's assertions that rampant continuation practice abuse is not supported by the record.

CONCLUSION

WHEREFORE, for all the foregoing reasons, Dr. Tafas respectfully moves the Court to grant Tafas summary judgment in his favor, along with such other, further and different relief as the Court deems just, equitable and proper.

Of Counsel:

William R. Golden Jr., Esq.
Susan Park, Esq.
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178-0002
Telephone: (212) 808-7992
Facsimile: (212) 808-7897
E-mail: wgolden@kelleydrye.com

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Respectfully submitted

/ Joseph D. Wilson ____________
Joseph D. Wilson (VSB # 43693)
Joanna Baden-Mayer (VSB # 67920)
Steven J. Moore, Esq. *(pro hac vice)*
James E. Nealon *(pro hac vice)*
KELLEY DRYE & WARREN LLP
Washington Harbor, Suite 400
3050 K Street, NW
Washington, DC 20007
Telephone: (202) 342-8400
Facsimile: (202) 342-8451
E-mail: jwilson@kelleydrye.com
jnealon@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas

CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2008 I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

Elizabeth Marie Locke
Kirkland & Ellis LLP
655 15th Street, NW, Suite 1200
Washington, DC 20005
Email: elocke@kirkland.com

Craig Crandell Reilly
Richard McGettingan Reilly & West PC
1725 Duke Street, Suite 600
Alexandria, VA 22314
Email: craig.reilly@rmrwlaw.com

Daniel Sean Trainor
Kirkland & Ellis LLP
655 15th Street, NW, Suite 1200
Washington, DC 20005
Email: dtrainor@kirkland.com

Counsel for Plaintiffs SmithKline Beecham Corp. d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Email: to'brien@morganlewis.com

Counsel for Amicus American Intellectual Property Lawyers Association

Dawn-Marie Bey
Kilpatrick Stockton LLP
700 13th Street NW
Suite 800
Washington, DC 20005
Email: dbey@kslaw.com

Counsel for Amicus Hexas, LLC, The Roskamp Institute, Tikvah Therapeutics, Inc.

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Avenue NW
Washington, DC 20004
Email: james.dowd@wilmerhale.com

Counsel for Amicus Pharmaceutical Research and Manufacturers of America

Randall Karl Miller
Arnold & Porter LLP
1600 Tysons Blvd, Suite 900
McLean, VA 22102
Email: randall_miller@aporter.com

Counsel for Amici Biotechnology Industry Organization and Monsanto Company

Rebecca M. Carr
Pillsbury Winthrop Shaw Pittman, LLP
2300 N Street, NW
Washington, DC 20037
Email: Rebecca.carr@pillsburylaw.com

Scott J. Pivnick
Pillsbury Winthrop Shaw Pittman
1650 Tysons Boulevard
McLean, Virginia 22102-4856
Email: Scott.pivnick@pillsburylaw.com

Counsel for Amicus Elan Pharmaceuticals, Inc.

Robert Christian Bertin
Swidler Berlin LLP
3000 K Street, NW, Suite 300
Washington, DC 20007
Tel: (202) 373-6672
Email: r.bertin@bingham.com

Counsel for Amicus Bar Association of the District of Columbia

Robert C. Gill
Saul Ewing LLP
2600 Virginia Avenue, NW, Suite 1000
Washington, DC 20037
Tel: (202) 295-6605
Fax: (202) 295-6705
Email: rgill@saul.com

Counsel for Amici BioAdvance, Life Sciences Greenhouse of Central Pennsylvania, and Pittsburgh Life Sciences Greenhouse

Matthew Schruers
Computer & Communications
Industry Association
900 17th Street, NW, Suite 1100
Washington, DC 20006
Tel.: (202) 783-0070
Fax: (202) 783-0534
Email: mschruers@ccianet.org

Counsel for Amici Public Patent Foundation, Computer & Communications Industry Association, AARP, Consumer Federation of America, Essential Action, Foundation for Taxpayer and Consumer Rights, Initiative for Medicines, Access & Knowledge, Knowledge Ecology International, Prescription Access Litigation, Public Knowledge, Public Patent Foundation, Research on Innovation, and Software Freedom Law Center

Kenneth Carrington Bass, III
Sterne, Kessler, Goldstein & Fox
1100 New York Avenue, NW, Suite 600
Washington, DC 20005
Tel: (202) 722-8825
Fax: (202) 371-2540
Email: kbass@skgf.com

Mark Fox Evens
Thelen, Reid & Priest, LLP
701 Eighth Street, NW, Fifth Floor
Washington, DC 20001-3721
Tel: (202) 722-8888
Email: mevens@skgf.com
Counsel for Amici AmberWave Systems Corporation, Fallbrook Technologies, Inc., InterDigital Communications LLC, Nano-Terra Inc., and Tessera, Inc.

Robert E. Scully Jr.
Stites & Harbison PLLC
1199 North Fairfax Street, Suite 900
Alexandria, Virginia 22314
(703) 739-4900
Fax: (703) 739-9577
Email: rscully@stites.com

Counsel for Amicus Human Genome Sciences, Inc.

Charles Gorenstein
Birch, Stewart, Kolasch and Birch, LLP
8110 Gatehouse Rd., Suite 100 East
Falls Church, Virginia 22042
Email: cg@bskb.com

Counsel for Amicus Intellectual Property Institute of the William Mitchell College of Law

Lauren A. Wetzler
Assistant United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22134
Tel: (703) 299-3752
Fax: (703) 299-3983
Email: Lauren.Wetzler@usdoj.gov

Counsel for All Defendants

Jonathan Dyste Link
Townsend and Townsend and Crew LLP
1301 K Street, NW, 9th Floor – East Tower
Washington, DC 20005
Tel: (202) 481-9900
Fax: (202) 481-3972
Email: jlink@townsend.com

Counsel for Amicus CFPH, LLC

Blair Elizabeth Taylor
Covington & Burling
1201 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: (202) 662-5669
Fax: (202) 778-5669
Email: btaylor@cov.com

Counsel for Amicus Intellectual Property Owners Association

Kevin Michael Henry
Sidley Austin Brown & Wood LLP
1501 K Street, NW
Washington, DC 20005
Tel: (202) 736-8000
Email: khenry@sidley.com

Counsel for Amicus Washington Legal Foundation

John C. Maginnis, III
1350 Connecticut Avenue, NW, Suite 301
Washington, DC 20036
Tel: (202) 659-4420
Email: maginnislaw2@verizon.net

Counsel for Amicus CropLife America

Jackson David Toof
Robins, Kaplan Miller & Ciresi LLP
1875 Eye Street, NW, Suite 300
Washington, DC 20006
Tel: (202) 857-6130
Fax: (202) 223-8604
Email: toof.jackson@arentfox.com

Counsel for Amici Anchor Wall Systems, Inc., Donaldson Company, Inc., Ecolab, Inc., General Mills, Inc., and Valspar Corporation

Timothy A. Molino
Bingham McCutchen LLP
2020 K Street, NW
Washington, DC 2006
Tel: (202) 373-6161
Fax: (202) 373-6001
Email: timothy.molino@bingham.com

Counsel for Amicus Federation Internationale Des Conseils En Proprit Industrielle

Craig James Franco
Odin Feldman & Pittleman PC
9302 Lee Highway, Suite 1100
Fairfax, VA 22031
Tel: (703) 218-2100
Email: craig.franco@ofplaw.com

Counsel for Amici Norseman Group, LLC and Polestar Capital Associates, LLC

David Wayne Long
Howrey Simon Arnold & White LLP
1299 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: (202) 783-0800
Email: longd@howrey.com

Counsel for Amicus Teles AG Informationstechnologien

Maurice Francis Mullins
Spotts Fain PC
411 E Franklin Street, Suite 600
PO Box 1555
Richmond, VA 23218
Tel: (804) 697-2069
Fax: (804) 697-2169
Email: cmullins@spottsfain.com

Counsel for Amici Intel Corporation and Micron Technology, Inc.

I have also caused copies of the foregoing, with attachments, to be sent to the following non-ECF users by first-class mail (where an address has been proved to the Court) or electronic mail (where it has not been):

Ron D. Katnelson
Encinatas, CA
rkatznelson@roadrunner.com

Amicus curiae Pro Se

Robert Lelkes
Geigenbergerstr.3
81477 Munich
Germany

Amicus Curiae Pro Se

Jennifer Sue Martinez
Stanford Law School
599 Nathan Abbott Way
Stanford, CA 94305
Tel: (650) 725-2749

Counsel for Amicus Intellectual Property and Administrative Law and Public Health Professors

___/s/ Joseph D. Wilson__________
Joseph D. Wilson (VSB # 43693)
KELLEY DRYE & WARREN LLP
Washington Harbor, Suite 400
3050 K Street, NW
Washington, DC 20007
Telephone: (202) 342-8400
Facsimile: (202) 342-8451
E-mail: jbaden-mayer@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas